Phase II Awards

NOTE: The Solicitations and topics listed on this site are copies from the various SBIR agency solicitations and are not necessarily the latest and most up-to-date. For this reason, you should use the agency link listed below which will take you directly to the appropriate agency server where you can read the official version of this solicitation and download the appropriate forms and rules.

The official link for this solicitation is: http://grants.nih.gov/grants/guide/pa-files/PAR-08-235.html

Agency:
Department of Health and Human Services

Release Date:
August 12, 2008
Branch:
n/a

Open Date:
August 12, 2008
Program / Phase / Year:
SBIR / Phase I / 2011

Application Due Date:
September 08, 2011

Solicitation:
PAR-08-235

Close Date:
September 08, 2011
Topic Number:
3

Description:

The scope of a Phase II award in the program is the same whether it is based on a previously successful Phase I in the regular SBIR program or if it is part of a Fast-Track application.

For entry to the program, projects must have one or more identified therapeutic leads and convincing proof-of-principle on efficacy demonstrated in credible models of the disease or against defined disease targets.

When appropriate, projects must include lead optimization for disease-related activity and for pharmacological and toxicological properties consistent with the intended use of the therapy, which is the subject of a special review criterion. In cases where no lead optimization is proposed, there must be a demonstration that sufficient optimization for the disease target and intended use have been conducted previously.

In addition to optimization, projects may include pre-clinical efficacy testing, predictive ADMET (absorption, distribution, metabolism, excretion, and toxicology) testing, formulation, manufacture, pharmacology, toxicology, and IND or IDE submission. Applications must include feasible plans for achieving a complete IND or IDE application for submission to the FDA within the project period. Because the project must be sufficiently advanced at entry to achieve regulatory submission by the end of the project period, the program does not support early-stage therapeutic discovery activities such as high throughput screening.

Due to the unique requirements of the NINDS Cooperative Program in Translational Research, applicants are strongly encouraged to consult with NINDS Program Staff as plans for an application are being developed. This early contact will provide an opportunity to clarify the applicant's understanding of program goals and guidelines, including the scope of projects within the program and the requirement that project objectives be milestone-driven. These discussions also provide important information and guidance on how to develop an appropriate milestone plan, which is subject to peer review under this program. Pre-application consultation includes both an introductory call to discuss the scope and goals of the program and a conference call with NINDS staff. Pre-application consultation on translational research cooperative agreements require adequate lead time before an application receipt date in order for applicants to have sufficient time to consider advice and perspective from NINDS program staff. For this reason, the introductory call should be completed at least 10 weeks before a receipt date and the conference call at least 8 weeks before a receipt date.

Shortly after receipt, applications will be examined by NINDS Program Staff to determine if they are within the scope of this FOA. PDs/PIs for applications that are outside the scope will be asked to consider whether their proposed studies fall within the scope of other FOAs. If an application is responsive to a different FOA that will be reviewed by the NIH Center for Scientific Review, it is likely the review will be delayed one round. Applications that are not within the scope of any existing FOAs will be withdrawn from further consideration.